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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,470	11/20/2001	Ruey S. Liou	TNX99-05-01	3795

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EXAMINER	
WEHBE, ANNE MARIE SABRINA	
ART UNIT	**PAPER NUMBER**
1632	

DATE MAILED: 05/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action	Application No.	Applicant(s)	
	09/991,470	LIOU ET AL.	
	Examiner	Art Unit	
	Anne Marie S. Wehbe	1632	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 24 March 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *see attached.*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☐ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *17, 19, 21-27*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

ATTACHMENT TO ADVISORY ACTION

5. cont. The rejection of claims 17, 19, and 21-27 under 35 U.S.C. 103(a) as being unpatentable over by U.S. Patent No. 6,066,718 (5/23/00), hereafter referred to as Hardman et al., in view of Whittington et al. (1998) Gene therapy Vol. 5 (6), 770-777, and U.S. Patent No. 6,468,547 (10/22/02), hereafter referred to as Buchsbaum et al., stands. Applicant's arguments have not been found persuasive. The applicant argues that there is no motivation to substitute a nucleic acid encoding anti-IgE antibody for the nucleic acids encoding anti-cancer antibodies in the recombinant adenoviruses taught by Whittington or Buchsbaum, particularly in view of the teachings in Whittington for antibody cytokine fusion protein as opposed to antibodies alone, because the antibodies of Whittington and Buchsbaum are anti-cancer antibodies and are not analogous to an antibody against IgE mediated allergic disease. In response, it is noted that the primary reference in this rejection is Hardman. Hardman teaches nucleic acids encoding the exact anti-IgE antibody claimed by the applicants. Further, Hardman et al. teaches that the anti-IgE antibodies encoded by these nucleic acids can be used to treat or prevent allergic diseases *in vivo,* and that the therapeutic effect of the antibodies stems from their ability to bind free IgE and inhibit the binding of IgE to the IgE receptors, including the high-affinity IgE receptor (Hardman et al., column 21-22, lines 49-67 and lines 1-25). Thus, Hardman et al. already teaches that these anti-IgE antibodies have therapeutic utility *in vivo*. The only thing missing in Hardman et al. is the teaching to use the nucleic acids encoding the anti-IgE antibody directly *in vivo* instead of administering the protein antibody made from the nucleic acid *in vitro*. Both Whittington et al. and Buchsbaum et al. were cited for teaching that the technology for expressing antibodies *in vivo* , particularly using adenoviral vectors, was well-established at the time of filing. Whittington et al. was also cited as providing clear motivation for expressing an antibody using a recombinant adenoviral vector *in vivo* over directly administering the protein antibody. Specifically, Whittington et al. teaches that "Antibodies and their recombinant fragments have enormous potential for therapy of malignant and other diseases, but there can be problems associated with their production and purification in the quantities required for therapeutic

use" which can be overcome by using recombinant nucleic acids to express the antibody *in vivo* (Whittington et al., page 770). Whittington et al. also teaches that an additional advantage to expressing the antibody using a recombinant vector rather than directly administering the antibody is the extended expression of the antibody *in vivo* for longer periods of time without readministration (Whittington et al., page 774, column 1, second paragraph). While the exact antibody taught by Whittington is part of a fusion protein, the motivation for administering nucleic acids over proteins applies to all types of antibodies. Further, Buchsbaum et al. clearly demonstrates the expression of therapeutic levels of a non-fusion protein single-chain antibody by administering an adenovirus encoding a single-chain antibody (Buchsbaum et al., column 17, lines 14-19). Thus, Whittington et al. and Buchsbaum et al. provides motivation to administer a nucleic acid encoding an antibody over administering the antibody itself, and further provide motivation for administering adenoviral vectors encoding the antibody. Since Hardman et al. already provides the teachings for treating allergic disease using anti-IgE antibodies, it would therefore have been *prima facie* obvious to the skilled artisan to administer the nucleic acids encoding anti-IgE antibodies taught by Hardman et al. using the adenoviral vectors taught by Whittington et al. and Buchsbaum et al. to treat allergic disease in an individual.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. The examiner can be reached Monday- Friday from 10:30-7:00 EST. If the examiner is not available, the examiner's supervisor, Amy Nelson, can be reached at (571) 272-0804. For all official communications, the technology center fax number is (703) 872-9306. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737.

Dr. A.M.S. Wehbé

ANNE M. WEHBE' PH.D
PRIMARY EXAMINER